0590 #3



## PATENT ATTORNEY DOCKET NO. 50010/017003

Certificate of Mailing: Date	of Deposit: June 20, 2001
	correspondence is being deposited with the United States Postal on the date indicated above and is addressed to the Assistant
Commissioner for Patents, Washington, D.C. 20:	
Commissioner for ratelits, washington, D.C. 20.	I MA
Susan M. Barry	Signature of person mailing correspondence
Printed name of person mailing correspondence	Signature of person mailing correspondence

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Douglas A. Treco et al.

Art Unit:

Not Yet Assigned

Serial No.:

09/845,020

Examiner:

Not Yet Assigned

Filed:

April 27, 2001

Customer No.:

21559

Title:

Genomic Sequences for Protein Production and Delivery

Assistant Commissioner For Patents Washington, DC 20231

## INFORMATION DISCLOSURE STATEMENT

Applicants submit the references listed on the enclosed Form PTO-1449.

Submission of this statement is not a representation that a search has been made, nor is information included in this statement an admission that the information is material to patentability.

Under 35 U.S.C. § 120, this application relies on the earlier filing date of application serial number 09/305,384, filed on May 5, 1999. The following references were submitted to the Office in the prior application and, therefore, are not provided in this application:

U.S. Patent No. 5,641,670

U.S. Patent No. 5,733,761

WO 95/31560

Arakawa et al., "Structure and Activity of Granulocyte Colony-stimulating Factor Derived From CHO Cells Containing cDNA Coding For Alternatively Spliced Sequences," Archives of Biochemistry and Biophysics 316:285-289 (1995).

Editorial, Nature Biotechnology 15:815 (1997).

Han et al., "Cloning and Expression of the cDNA Encoding Rat Granulocyte Colony-Stimulating Factor," Gene 175:101-104 (1996).

Kershaw et al., "Human DNA Sequence from Cosmid U221F2 on Chromosome X. Contains ESTs and STS," EMBL Database Entry HSU221F2, Accession Number Z75746, XP002110689, Abstract (1996).

Kuczek et al., "A Granulocyte-Colony-Stimulating Factor Gene Promoter Element Responsive to Inflammatory Mediators Is Functionally Distinct from an Identical Sequence in the Granulocyte-Macrophage Colony-Stimulating Factor Gene," The Journal of Immunology 146:2426-2433 (1991).

Kulmburg et al., "Cloning and Sequence Analysis of the Immediate Promoter Region and cDNA of Porcine Granulocyte Colony-stimulating Factor," Gene 197:361-365 (1997).

Leizer et al., "Cytokine Regulation of Colony-Stimulating Factor Production in Cultured Human Synovial Fibroblasts: I. Induction of Gm-CSF and G-CSF Production by Interleukin-1 and Tumor Necrosis Factor," Blood 76:1989-1996 (1990).

Monaco et al., "Expression of Recombinant Human Granulocyte Colony-Stimulating Factor in CHO dhfr Cells: New Insights into the In Vitro Amplification Expression System," Gene 180:145-150 (1996).

Nagata, Granulocyte Colony-Stimulating Factor, In: Peptide Growth Factors and Their Receptors, Sporn and Roberts (eds.), Springer-Verlag New York, NY 699-722 (1991).

Nagata et al., "Molecular Cloning and Expression of cDNA for Human Granulocyte Colony-Stimulating Factor," Nature 319:415-418 (1986).

Nagata et al., "The Chromosomal Gene Structure and Two mRNAs for Human Granulocyte Colony-Stimulating Factor," The EMBO Journal, 5:575-581 (1986).

Nishizawa et al., "Regulatory Elements Responsible for Inducible Expression of the Granulocyte Colony-Stimulating Factor Gene in Macrophages," Molecular and Cellular Biology 10:2002-2011 (1990).

Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," National Institutes of Health (1995).

Reidhaar-Olson et al., "Identification of Residues Critical to the Activity of Human Granulocyte Colony-Stimulating Factor," Biochemistry 35:9034-9041 (1996).

Rotondaro et al., "High-level Expression of a cDNA for Human Granulocyte Colony-Stimulating Factor in Chinese Hamster Ovary Cells. Effect of 3'-noncoding Sequences," Molecular Biotechnology 7:231-240 (1997).

Stanley et al., "The Structure and Expression of the Murine Gene Encoding Granulocyte-Macrophage Colony Stimulating Factor: Evidence for Utilisation of Alternative Promoters," The EMBO Journal 4:2569-2573 (1985).

Tweardy et al., "Molecular Cloning and Characterization of a cDNA for Human Granulocyte Colony-Stimulating Factor (G-CSF) from a Glioblastoma Multiforme Cell Line and Localization of the G-CSF Gene to Chromosome Band 17q21," Oncogene Research 1:209-220 (1987).

Tweardy et al., "Molecular Cloning of cDNAs for the Human Granulocyte Colony-Stimulating Factor Receptor from HL-60 and Mapping of the Gene to Chromosome Region 1p32-34," Blood 79:1148-1154 (1992).

Verma et al., "Gene Therapy - Promises, Problems, and Prospects," Nature 389:239-242 (1997).

If there are any charges or any credits, please apply them to Deposit Account

No. 03-2095.

Respectfully submitted,

Date:

June 20, 2001

Susan M. Michaud, Ph.D.

Reg. No. 42,885

Clark & Elbing LLP 176 Federal Street Boston, MA 02110

Telephone: 617-428-0200 Facsimile: 617-428-7045

50010.017003 Information Disclosure Statement.wpd

PATENT TRADEMARK OFFICE

21559



Sheet <u>1</u> of \_\_;

<u> </u>						Oncer		
SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMME (MODIFIED) PATENT AND TRADEMARK OF						50010/017003		
			J TRADEMARK OF TICE	Serial No.		09/845,020		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)				Applicant		Douglas A. Treco et al.		
			Filing Date		April 27, 2001			
			sary)	Group		Not Yet Assigned		
(37 C.F.R. §1.98(b))				IDS Filed		June 20, 2001		
				Customer No.		21559		
			U.S. PATENTS					
Examiner's Initials	Patent Number	Issue Date	Patentee		Class	Subclass	Filing Date (If Appropriate)	
	5,641,670	06/24/97	Treco et al.		435	240.2		
	5,733,761	03/31/98	Treco et al.			172.3		
FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION								
Examiner's Initials	Document Number	Publication Date		Country or Patent Office		Subclass	Translation (Yes/No)	
	WO 95/31560	11/23/95	РСТ					
	OTHER DOCU	MENTS (INCL	JDING AUTHOR, TITLE,	DATE, PLAC	E OF PUB	LICATION)		
	Arakawa et al., "Structure and Activity of Granulocyte Colony-Stimulating Factor Derived From CHO Cells Containing cDNA Coding For Alternatively Spliced Sequences," Archives of Biochemistry and Biophysics 316:285-289 (1995).							
	Editorial, Nature Biotechnology 15:815 (1997).							
	Han et al., "Cloning and Expression of the cDNA Encoding Rat Granulocyte Colony-Stimulating Factor," Gene 175:101-104 (1996).							
	Kershaw et al., "Human DNA Sequence from Cosmid U221F2 on Chromosome X. Contains ESTs and STS," EMBL Database Entry HSU221F2, Accession Number Z75746, XP002110689, Abstract (1996).							
Kuczek et al., "A Granulocyte-Colony-Stimulating Factor Gene Promoter Element Responsive to Inflammatory Mediators is Functionally Distinct from an Identical Sequence in the Granulocyte-Macrophage Colony-Stimulating Factor Gene," The Journal of Immunology 146:2426-2433 (1991).								
Kulmburg et al., "Cloning and Sequence Analysis of the Immediate Promoter Region and cDNA of Porcine Granulocyte Colony-Stimulating Factor," Gene 197:361-365 (1997).								
Leizer et al., "Cytokine Regulation of Colony-Stimulating Factor Production in Cultured Human Synovial Fibroblasts: I. Induction of Gm-CSF and G-CSF Production by Interleukin-1 and Tumor Necrosis Factor," Blood 76:1989-1996 (1990).								
Monaco et al., "Expression of Recombinant Human Granulocyte Colony-Stimulating Factor in CHO dhfr Cells: New Insights into the In Vitro Amplification Expression System," Gene 180:145-150 (1996).								
EXAMINER			DATE C	ONSIDERED	)			
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.								



Sheet 2 of 2

				Officet Z Of Z			
	FORM PTO-1449 U.S. DEPARTMENT OF COMMI			50010/017003			
(MODIFIED) PATENT AND TRADEMARK OFF		FICE	Serial No.	09/845,020			
INFORMATION DISCUSSION			Applicant	Douglas A. Treco et al.			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)  (37 C.F.R. §1.98(b))			Filing Date	April 27, 2001			
			Group	Not Yet Assigned			
			IDS Filed	June 20, 2001			
			Customer No.	21559			
	OTHER DOCUMENTS (INCLUDING AUTHOR, T	TTLE, D	ATE, PLACE OF PUBL	CATION)			
	Nagata, Granulocyte Colony-Stimulating Factor, In: Peptide Growth Factors and Their Receptors, Sporn and Roberts (eds.), Springer-Verlag New York, NY 699-722 (1991).						
	Nagata et al., "Molecular Cloning and Expression of cDNA for Human Granulocyte Colony-Stimulating Factor," Nature 319:415-418 (1986).						
	Nagata et al., "The Chromosomal Gene Structure and Two mRNAs for Human Granulocyte Colony-Stimulating Factor," The EMBO Journal, 5:575-581 (1986).						
	Nishizawa et al., "Regulatory Elements Responsible for Inducible Expression of the Granulocyte Colony- Stimulating Factor Gene in Macrophages," Molecular and Cellular Biology 10:2002-2011 (1990).						
	Orkin et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," National Institutes of Health (1995).						
	Reidhaar-Olson et al., "Identification of Residues Critical to the Activity of Human Granulocyte Colony- Stimulating Factor," Biochemistry 35:9034-9041 (1996).						
	Rotondaro et al., "High-level Expression of a cDNA for Human Granulocyte Colony-Stimulating Factor in Chinese Hamster Ovary Cells. Effect of 3'-noncoding Sequences," Molecular Biotechnology 7:231-240 (1997).						
	Stanley et al., "The Structure and Expression of the Murine Gene Encoding Granulocyte-Macrophage Colony Stimulating Factor: Evidence for Utilisation of Alternative Promoters," The EMBO Journal 4:2569-2573 (1985).						
	Tweardy et al., "Molecular Cloning and Characterization of a cDNA for Human Granulocyte Colony-Stimulating Factor (G-CSF) from a Glioblastoma Multiforme Cell Line and Localization of the G-CSF Gene to Chromosome Band 17q21," Oncogene Research 1:209-220 (1987).						
	Tweardy et al., "Molecular Cloning of cDNAs for the Human Granulocyte Colony-Stimulating Factor Receptor from HL-60 and Mapping of the Gene to Chromosome Region 1p32-34," Blood 79:1148-1154 (1992).						
	Verma et al., "Gene Therapy - Promises, Problems, and Prospects," Nature 389:239-242 (1997).						
EXAMINER	עם	ATE CO	NSIDERED				
	nitial citation considered. Draw line through citation if next communication to applicant.	not in co	onformance and not con-	sidered. Include copy of this			